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Guidelines
for Assessing the Toxic Hazard of
Spacecraft Chemicals and Test Materials

Toxicology Group

Medical Operations Branch

Medical Sciences Division

Space and Life Sciences Directorate

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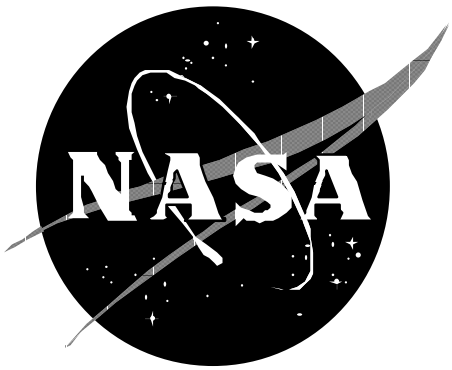

National Aeronautics and Space Administration

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Houston, Texas

Guidelines for Assessing the Toxic Hazard of Spacecraft Chemicals and Test Materials

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List of Acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ARS	Air Revitalization System
CDAE	Carbon Dioxide Absorbent Element
CHX	Condensing Heat Exchanger
DSO	Detailed Supplementary Objective
DTO	Development Test Objective
EPA	United States Environmental Protection Agency
ESA	European Space Agency
FA	Formaldehyde
FRD	Flight Requirements Document
GA	Glutaraldehyde
GFE	Government Furnished Equipment
HIV	Human Immunodeficiency Virus
HMST	Hazardous Material Summary Table
HRPPC	Human Research Policy and Procedures Committee *(now called the IRB)*
IRB	Institutional Review Board *(replaced the HRPPC at JSC)*
JSC	Lyndon B. Johnson Space Center
JSC-TG	NASA/JSC Toxicology Group
LiOH	Lithium Hydroxide
N/A	Not Applicable
NASA	National Aeronautics and Space Administration
Osm	Osmolar
OVC	Orbiter Vacuum Cleaner
PFA	Paraformaldehyde
PILS	Payload Integration Library System
PSRP	Payload Safety Review Panel
RME	Risk Mitigation Experiment
SEBS	Spacelab Emergency Breathing System
SMAC	Spacecraft Maximum Allowable Concentration
THL	Toxic Hazard Level
TLV	Threshold Limit Value

1. Introduction

1.01 Purpose and Scope of This Document

This document describes the criteria and procedural guidelines used by the NASA/JSC Toxicology Group (JSC-TG) to perform toxicological evaluations. The JSC-TG is responsible for conducting toxicological assessments and assigning toxic hazard levels for essentially all chemicals and biological materials that are used or transported in the habitable areas of U.S. spacecraft, including chemicals and biologicals carried by the Space Shuttle to and from the Mir and International Space Station (ISS). Hazard assessments for microorganisms used in payload experiments are performed at the request of the JSC-TG by the JSC Microbiology Laboratory. Radioactive materials are assessed by the JSC Radioisotope Working Group for radiation risk; the flammability rating on flammable materials is assessed by the Nonmetallic Materials Branch. This document will focus on the assessment of chemically-induced toxicity hazards. The toxicologic assessments, together with assessments on radioactive, microbiological, and flammability hazards, are incorporated into a mission-specific Hazardous Materials Summary Table (HMST).

1.02 Purpose of Toxic Hazard Assessments and the Hazardous Material Summary Table

Safety is of the highest priority to NASA. Thus, minimizing adverse effects on crew health from exposure to hazardous materials in spacecraft is a major NASA objective. In supporting NASA's safety objective, the JSC-TG assumes responsibility for compiling information on, assessing the potential adverse effects of, and assigning toxic hazard levels to all in-flight chemicals/materials to which the crew might be exposed. These include all test sample materials reviewed by the NASA Payload Safety Review Panel (PSRP) for use or transport in the pressurized volume of the Orbiter as well as other potentially toxic materials not reviewed by the PSRP which may include utility chemicals and those in government furnished equipment (GFE), risk mitigation experiments (RMEs), Development Test Objectives (DTOs), etc. The assigned hazard levels are used by payload developers as criteria in the design of flight hardware to assure adequate containment. For experiments and other payloads flying in the pressurized volume of the Shuttle, it is the responsibility of the PSRP to certify that the design of equipment provides adequate containment for the toxicity hazard level of the materials it contains. Experimenters are required to label their hardware or sample containers according to the toxic hazard levels assigned to the contents, so that crew members can know immediately if an escaped material poses a toxicity concern. The assigned medical protocols in the

HMST will help the crewmembers and flight surgeons to respond appropriately in the event of exposure to hazardous materials.

1.03 Compilation and Distribution of Toxicological Hazard Information

The assessment process begins with payload investigators, managers, or coordinators (collectively termed as payload customers) submitting information and relevant data to the JSC-TG on payload chemicals as described in *Requirements for Submission of Test Sample Material Data for Payload Safety Evaluation* (JSC 27472) or its subsequent revisions. The relevant data, together with the toxicological assessments and assigned toxic hazard levels, are entered into a computerized database from which is printed an HMST. Printed copies of the relevant pages of the HMST are provided to payload customers and the PSRP for supporting safety assessments for payload hardware. The appropriate sections of the HMST for a particular mission are provided to payload customers to verify the accuracy of the information on chemicals they intend to fly. After verification, the final HMST is provided to flight surgeons and other mission support personnel. Copies of the HMST are used by payload customers to verify sample loading prior to payload hardware turnover for Shuttle stowage. Before a Shuttle launch, the data from the HMST for that mission are transferred to a mission-specific electronic file, which is provided to mission support personnel for loading onto the Shuttle onboard portable general support computers and the flight surgeon's computer in the Mission Control Center to provide real-time toxicological support.

2. Definition of Toxic Hazard Levels (THLs)

Definitions of toxic hazard levels and recommended responses to accidental releases of hazardous materials have been incorporated into Flight Rule 13-22, "Hazardous Substance Spill Response" (Appendix 5.01). The toxicological provisions of this flight rule are summarized in Table 1. The hazard levels were defined operationally by a working group comprised of representatives from the Astronaut Office, flight surgeons, the JSC-TG, and the Mission Operations Directorate.

The toxic hazard level of an escaped chemical depends on its physicochemical properties (e.g., gas, liquid, solid, particle size, acidity, alkalinity, and corrosiveness), its quantity, its biological effects (e.g., irritancy, carcinogenicity, systemic toxicity), and the ease with which the chemical is removed from the environment. The removal rate depends on a combination of the characteristics of the Spacecraft's life support system and the chemical's physicochemical properties (see Appendix 5.02).

Table 1.

Criteria for Assignment of Toxicological Hazard Levels and Color Codes

Hazard Level	Irritancy	Systemic Effects	Containability and Decontamination
0 (Non hazard) (green)	Slight irritation that lasts <30 minutes and will not require therapy.	None	Gas, solid, or liquid may or may not be containable.
1 (Critical) (blue)	Slight to moderate irritation that lasts >30 min and will require therapy	Minimal effects, no potential for lasting internal tissue damage.	Gas, solid, or liquid may or may not be containable. However, the crew will be protected from liquids and solids by surgical masks, gloves, and goggles.
2 (Catastrophic) (yellow)	Moderate to severe irritation that has the potential for long-term performance decrement and will require therapy. Eye Hazards: May cause permanent damage.	None	Either a solid or nonvolatile liquid. Can be contained by a cleanup procedure and disposed of. The crew will be protected by 5-micron surgical masks, gloves, and goggles.
3 (Catastrophic) (orange)	Irritancy alone does not constitute a level 3 hazard.	Appreciable effects on coordination, perception, memory, etc., or has the potential for long-term (delayed) serious injury (e.g. cancer), or may result in internal tissue damage.	Either a solid or nonvolatile liquid that can be contained by a cleanup crew and disposed of. Surgical masks and gloves will not protect the crew. Either quick-don masks or SEBS and gloves are required.
4 (Catastrophic) (red)	Moderate to severe irritancy that has the potential for long-term crew performance decrement (for eye-only hazards, there may be a risk of permanent eye damage). Note: Will require therapy if crew is exposed.	Appreciable effects on coordination, perception, memory, etc., or the potential for long-term (delayed) serious injury (e.g. cancer) or may result in internal tissue damage.	Gas, volatile liquid, or fumes that are not containable. The ARS will be used to decontaminate. Either the quick-don masks or the SEBs are required or the contaminated module will be evacuated.

3. General Guidelines by Which Toxicological Hazards and Toxic Hazard Levels Are Assessed.

Test materials can be solids, liquids, gases, or fine particulates. They can be pure chemicals, solutions, complex mixtures, metallic alloys, blood components, normal human or animal cells, human or animal cancer cells, microorganisms, plants, small animals, etc. During processing, test materials may undergo changes in phase (e.g. solid or liquid to vapor or fume), undergo chemical reactions to produce new chemicals (e.g. combustion), or undergo changes in concentration (e.g. dilution). Test materials can be classified as organic, inorganic, polymeric, biological, radioactive, acidic, basic, neutral, oxidants, hypertonic or hypotonic. These chemical, physical and biological properties, together with their intrinsic toxicity or biohazard potential, determine the hazard level of the test materials. Because the range of test materials is so broad, no one set of standard procedures describes how the JSC-TG assesses every possible test material. Some general guidelines described below are applicable for assessing most test materials. Other procedures applicable to individual classes of chemicals or materials are described in Section 4.

3.01 Identifying In-Flight Chemicals and Biologicals

The JSC-TG assesses the potential toxic hazards of chemicals and test materials used or contained in in-flight payload experiments, equipment, and hardware (e.g. GFE, crew escape equipment, etc.). Usually, the information on chemicals/test materials is provided to JSC-TG by mission managers, payload integration managers, or investigators. Payload customers generally are required to submit to the JSC-TG information on chemical identities, composition, physical states, concentrations, amount, test conditions and other relevant information, as specified in JSC 27472, as part of their safety data packages prepared for payload safety reviews. The sponsors of new GFE items should also submit this information on their chemicals/test materials to the JSC-TG.

The JSC-TG needs to know what payloads will be flying in a particular mission. Mission-specific Flight Requirements Documents (FRDs), published by the Flight Integration Office, contain a manifest of all payload experiments, DTOs, DSOs, RMEs, hardware, equipment, etc. for a particular mission. The PSRP Mission Assignment List and the Payload Assignment List by Payload (published by the Payload and Crew Equipment Assurance Branch) list the payload safety engineer and payload integration manager for a

particular payload. If information on the test materials of an experiment or a hardware has not been submitted, payload safety engineers could help JSC-TG to identify the payload customers from whom chemical information could be obtained.

Appendix 5.03 provides information on how the FRD and other relevant documents can be obtained from the Internet.

3.02 Assessing the Toxic Hazards of Released Chemicals

The toxic hazard level of a payload chemical is defined in terms of the risk to crew health from an accidental spill or leak of that chemical. It depends on the intrinsic toxicity and physical properties of the chemical without regard to physical containment. An exception to this rule is made for chemicals entrapped in a matrix that would definitely prevent their escape or rapid release. Such entrapment is considered by the toxicologist in setting the toxic hazard level. A payload customer may propose a triple containment for a highly toxic chemical to minimize its chance of release. This would not alter the toxic hazard of the chemical. It would, however, reduce the risk to the crew health. Assessment of the adequacy of containment is the purview of the PSRP.

If several containers in an experiment system hold identical chemicals, it is generally assumed that the chemicals in only one container (the one with the greatest amount) could escape unless a single mishap could credibly release chemicals from several containers.

3.03 Analyzing the Hazard of Chemical Mixtures

The toxic hazard of a mixture of chemicals is determined from the toxicity of the entire mixture or, if that is unknown, the most toxic component in that mixture.

3.04 Assessing Chemicals That Undergo Phase or Composition Changes During Processing or Concentration Changes After Mixing

If chemicals or mixtures pose different toxicological hazards to crew members before, during, or after these chemicals are processed, all of these stages are assessed. If a liquid is to be mixed with another liquid of a different toxic hazard level, then the resultant mixture also is assessed.

3.05 Calculating Potential Atmospheric Concentrations of Chemicals on the Spacecraft

When fine dusts, metallic fumes, gases, or vapors from volatile liquids escape in the spacecraft, these substances become airborne and are assumed to uniformly

disperse throughout the habitable volume**.** The toxic hazard of these chemicals will depend on the resultant cabin concentrations, which can be estimated by dividing the amount of escaped chemical by the relevant spacecraft volume. The approximate volumes of the various spacecraft modules, adjusted for the normal amount of equipment inside, are as follows:

Shuttle cabin		65 m^3
Spacelab		77 m^3
Spacehab single module (including short tunnel & shuttle cabin)		94 m^3
Spacehab double module (including tunnel & shuttle cabin)		134 m^3
Spacehab enhanced module (including tunnel & shuttle cabin)		100 m^3
Mir Space Station:		350 m^3
International Space Station (ISS):	US Lab (at launch configuration)	106 m^3
	US Lab (fully equipped)	100 m^3
	Japanese Experiment Module	125 m^3
	Docking & Stowage Module (two)	48 m^3 each
	ESA Columbus Module	77 m^3
	Functional Cargo Block	72 m^3
	Experiment modules (three)	48 m^3 each
	Life Support Module	48 m^3
	Progress Module	6.5 m^3
	Service Module	100 m^3
	Soyuz	10.5 m^3 each

3.06 Estimating the of Rate of Removal of an Escaped Chemical

The time needed for the air revitalization system (ARS) to remove specific types of toxicants depends on many factors. These include the amount of the chemical which escaped, its chemical and physical properties, the total volume of air to be scrubbed, the rate of cabin airflow through the various air scrubbers, the ability of the air scrubber's absorbent materials to retain specific contaminants, the mesh sizes of the air filters used to retain particulates, and the condensing and solution of vapors into water formed by the condensing heat exchanger (dehumidifier). Usually it is only possible to make a rough estimate of removal times or contaminant concentrations during and after scrubbing. More detailed information on the various ARS components is given in Appendix 5.02.

3.07 Identifying Potential Exposure Routes and Target Organs

Of the various ways in which crew members could be exposed to an escaped chemical, ingestion (i.e., oral route) is considered least likely because they would not open their mouths to allow the chemical to flow in and then swallow it. Therefore, this route of

exposure is generally not assessed except for the case of concentrated cultures of pathogenic microbes in liquid media. Most chemicals spilled on the skin can be readily removed; skin absorption is usually very slow. This route of exposure usually poses only minimal risk and is generally not considered except for the case of highly corrosive materials such as concentrated acids and bases and those few compounds, such as phenol, which are absorbed through the skin in sufficient quantity to cause systemic toxicity. Nonvolatile liquids are routinely assessed primarily for their eye irritancy. Any liquid reaching the eye could remain there for up to 6 minutes because it might take about that length of time to set up the eyewash station (opinion of crew surgeon). Since no more than about 0.5 ml of liquid could contact the eye due to its small surface area, small or large volumes of liquid would pose similar eye hazard levels.

Volatile liquids are assessed for their eye irritancy, and their vapors are assessed for irritancy to the eyes and respiratory tract and for systemic toxicity. The major concerns posed by metallic fumes, dusts, and gases are respiratory tract irritancy and systemic toxicity. Microorganisms and animal products (such as blood cells) are assessed for their infectious potential.

The allergenic potential of chemicals is generally not considered since the interaction among host, chemicals, and amounts are very difficult to predict or quantify.

3.08 Using SMACs and Threshold Limit Values (TLVs) in Determining THLs

NASA has established 1-hour, 24-hour, 7-day, 30-day and 180-day spacecraft maximum allowable concentrations (SMACs) for about 50 airborne chemicals. Generally, these exposure limits allow minor discomfort during 1-h or 24-h exposures and no discomfort or significant risk of toxicity for longer exposures. In addition, NASA has more than 400 official and unofficial 7-day SMACs.

The American Conference of Governmental Industrial Hygienists (ACGIH) has established TLVs for several hundred industrial chemicals. The TLVs are established to protect nearly all industrial workers exposed up to 8 hours per day, 40 hours per week for their entire working life, which could be 40 years long. A TLV value for nuisance dusts or low-toxicity particulates and metals may be established merely to protect against dust loading in the lung over many years.

NASA's Toxic Hazard Levels (THLs) (see Table 1) are based on the severity of eye irritancy, systemic toxicity, potential for permanent tissue injury, and the ability of the

crew and the spacecraft environmental control and life support system to decontaminate or remove that material.

Since SMACs, TLVs, and THLs are based on different criteria and are meant to be used in very different circumstances, no precise quantitative relationship exists between SMACs and THLs, or between TLVs and THLs, nor are there SMAC and TLV equivalents to the critical and catastrophic levels in the THL scale. However, there is usually a rough relationship among these three standards. For example, an exposure to a vapor rated as a critical hazard (THL=1) would have more serious toxicological effects than an exposure to the SMAC or TLV concentration of the same vapor. Therefore, if the potential spacecraft concentration of an airborne chemical is less than or equal to the TLV or SMAC, it is generally a 0 level hazard. The toxic hazard rating of concentrations greater than the TLV or SMAC will depend on the intrinsic toxicity and physicochemical properties of the chemical.

3.09 Determining the Intrinsic Toxicity

As discussed above, the physiochemical properties of test materials are very diverse and their toxicity can vary greatly. Toxicity is judged by available information from reference books, computerized toxicology databases, or assessments performed for past HMSTs. Material safety data sheets and information on the biochemistry and toxicity of the proposed chemicals obtained from the payload customers or chemical manufacturers may also be used. Information on structurally related compounds may be used to infer the toxic properties of the compound of interest. In some cases, little or no data are available for particular chemicals, and assessment requires a considerable amount of professional judgment and conservatism.

3.10 Assigning Toxic Hazard Levels

After all of the above relevant steps have been completed, a THL is assigned to the test material according the definitions specified in Table 1. If the THL of a test material cannot be readily assigned using these definitions, it is rated on the basis of the best match between the table definitions and the toxicological properties of the material. If the chemicals had been rated on previous missions, the same rating is applied. Occasionally, new data become available that may lead to a revision of previous hazard assessments and ratings. Assessments and ratings are generally based on agreement between two toxicologists.

4. Procedural Guidelines for Assessing the Toxicological Hazard Levels of Chemicals and Biological Agents

4.01 Metals and Metallic Compounds Used in Metallurgical (Furnace) Experiments

Metals and metallic compounds can vaporize when heated to high temperatures and condense into fumes and fine dusts upon cooling. The toxic hazard level depends on the amount and toxicity of the metallic vapors or fumes produced during processing. If the investigators can provide the evaporation rates of the metals in an alloy or estimated amounts of fumes that could be generated from the alloy during processing, or if they have data on sample weight loss due to heating of the naked alloy sample, JSC toxicologists will use these data for toxicity risk assessment. If calculated or experimental data are unavailable, JSC toxicologists will use the simplified Langmuir's Law for estimation of the evaporation rate, Q (in $mg/cm^2/second$) of the metals in the alloy.

$$Q = 43.7\ (M/T)^{0.5}P$$

M is the atomic weight (a.m.u.), of a given metal, T is the planned maximum processing temperature (°K), and P is the vapor pressure (mbar) of the metal at temperature T. P can be found from the literature or from a vapor pressure vs. temperature curve (see Appendix 5.04). The amount of fumes of a metal that could be generated during processing, A (mg), can be estimated as follows:

$$A = Q\ S\ t$$

where S is the surface area (cm^2) of the alloy occupied by that metal and t (seconds) is the processing time at the maximum (holding) temperature. For example, if the alloy contains 20% of metal X and has a surface area of 5 cm^2, the surface occupied by metal X is considered to be 1 cm^2. The amount of metal vapor generated during the heating and cooling phases is relatively small compared to that generated during the holding temperature, unless the holding time (at maximum temperature) is very short compared to the heating and cooling time. If the holding time is relatively short, the assessment will be evaluated case by case. If experimental data are not available, the investigators are encouraged to estimate the metallic fume production of their samples using the above formula or another more appropriate equation.

Depending of the circumstances of an experiment, the temperature used in the formula above could be either the nominal maximum planned temperature or the maximum "run-away" temperature (i.e., that caused by experimental or control failure). The JSC TG

generally uses the nominal maximum planned temperature for calculations unless directed by the PSRP to use the maximum run-away temperature for a given experiment.

From the calculated amounts of metallic fumes that could be generated from each metal in an alloy, the potential spacecraft cabin atmospheric concentrations of metallic fumes can be estimated in the event of their escape into the cabin as follows.

$$C = \frac{A}{V}$$

where A is the amount in mg of fumes, V is the spacecraft cabin volume in cubic meters and C is the concentration in mg/m^3 (see section 3.05). These concentrations are compared with the TLVs, or SMACs of these metals, if available. In 1990, upon the recommendation of the JSC toxicologist, the Chairman of the Human Research Policy and Procedures Committee (HRPPC) promulgated a guideline for a default approach for assessing the hazard levels of metal fumes (Appendix 5.05). A metal fume or dust concentration greater than or equal to 1x the TLV but < 10x the TLV would be considered a level 1 (critical) hazard. A fume concentration equal to or greater than 10 times the TLV value would be a level 4 (catastrophic) hazard. However, when toxicology data for the metal are available, more accurate assessment is possible and the default approach is not followed.

4.02 Particulates Other Than Metal Fumes or Dusts

If inorganic solids such as particles of charcoal or lithium hydroxide should escape in microgravity, they will become airborne and could be inhaled or come in contact with the eyes. The inhalation toxicity of these chemicals will depend mainly on their respirability, chemical reactivity, intrinsic toxicity, and irritancy. Generally, the finer the particles, the greater their ability to penetrate deep into the lung and cause injury. Particles of size ≤1 mm but > 5 μm tend to deposit in the upper respiratory tract, whereas sizes ≤ 5 μm tend to penetrate deeply into the lung. Larger particles (>0.1 mm) that are highly alkaline or acidic, or strong oxidants, are very corrosive to the eyes and are generally rated as catastrophic (toxicity level 2) eye hazards. Hard, rough inert particles ≥50 μm may be rated as level 1 (critical) eye hazards on the basis of possible traumatic eye irritation. Hard, rough inert particles <50 μm and hard, inert smooth particles > 5 μm are rated as nonhazards.

4.03 Gases

Gases stored in pressurized vessels are sometimes used in payload experiments. The potential hazard associated with the rupture of high-pressure vessels is assessed by the pressure vessels group in the JSC Materials and Failure Analysis Branch, EM2. The potential hazard of a gas is assessed based on the amount of that gas in the cylinder and its intrinsic toxicity. ARS removal rates may be factored into the toxicological assessment.

4.04 Organic Liquids

Liquids that are only slightly volatile or not volatile are assessed only for eye or skin irritancy and/or skin absorption. Volatile liquids are assessed as both liquid (eye) and vapor (eye and respiratory) hazards. A chemical that is a respiratory hazard can cause bronchitis or pneumonia due to respiratory irritation, or it may be absorbed from the lungs into the bloodstream and cause systemic effects such as liver or kidney injury. The potential for an organic liquid to be a vapor hazard is determined from its amount and its vapor pressure. If the vapor pressure of a liquid is low and it is not likely to escape into an inaccessible area, it is assumed that the crew would be able to remove it with an absorbent material (such as Kim Wipes) before a hazardous amount of vapor is released, so it would be only a liquid hazard.

4.05 Fixatives

Formaldehyde (FA), paraformaldehyde (PFA), and glutaraldehyde (GA) solutions are common biological fixatives used in payload experiments. PFA is a polymer of FA and is a solid. In neutral solutions, PFA exists in equilibrium with its dissociated form, FA. All three aldehydes are very irritating to the eyes. The eye irritancy of GA at different concentrations, as reported by the Union Carbide Corporation, is shown in Appendix 5.06. The JSC flight surgeons and toxicologists agree that solutions of FA or GA at concentrations of between 0.25% and 1% are level 1 eye hazards. FA or GA concentrations ≥1% are level 2 (catastrophic) eye hazards. Although FA and GA vapors are highly irritating to the respiratory tract, the vapor pressure of dilute solutions is relatively low. Like liquid organic chemicals having low volatility (see Section 4.04 above), it is usually assumed that if a single aliquot of dilute FA or GA solution were to escape, it could be cleaned up before a hazardous amount of vapor was released. FA vapor at less than 0.4 ppm is assigned a THL of 0. FA vapor concentrations between 0.4 and 9.9 ppm are assigned a THL of 1. If the potential spacecraft cabin vapor concentrations of FA are greater than or equal to 10 ppm, they could be very irritating or life threatening, and a THL of 4 (catastrophic vapor) is assigned.

4.06 Acids, Bases, and Buffer Solutions

Strong acids and bases are corrosive and can cause severe irritation and permanent damage to the eyes. Buffered solutions of acids and bases are more irritating than unbuffered solutions of the same pH. At the same concentration in water, a strong acid (e.g. HCl, H_2SO_4), which is fully ionized to produce a low pH solution, is more corrosive to the surface of the eye than a weak acid (e.g. acetic acid, CH_3COOH), which is only partially ionized and produces a higher pH solution. However, the non-ionized (lipophilic) species, which can penetrate the intact corneal epithelium, is capable of causing damage to the inner structures of the eyes. The epithelium provides a barrier to charged ions and large molecules; however, if the epithelial layer is damaged (e.g., by a strong acid), the underlying structure is vulnerable to damage by the acid. Generally, at the same pH, weak organic acids (e.g. acetic acid) are more injurious to the eye than strong inorganic acids, such as HCl. Therefore, the potential eye hazards of acids are evaluated case by case. Appendix 5.07 contains information on the pH of some common acids and bases. If no toxicity information is available on the acid or base, the default hazard levels listed in Table 2 will be used.

Table 2
Eye Hazard Assessments Based on pH Levels

Hazard level	Acids (Inorganic)	Acidic Buffers (organic)	Bases	Basic Buffers
0*	> 3	> 5	<10	<9.5
1	2.1-3.0	2.6 - 5.0	10.0 - 11.4	9.5 - 10.9
2	≤2.0	≤2.5	≥11.5	≥ 11

*Neutral, weakly acidic, and weakly basic solutions are assessed a hazard level 0 (nonhazard) provided that they are not highly reactive, toxic or hypertonic (see Salt Solutions, below).

4.07 Salt Solutions

Hazards from salt solutions can be due to their hypertonicity, corrosiveness, or idiopathic toxicity. Hypertonic salt solutions can cause eye discomfort. Isotonic saline contains 155 mM (310 mOsm, or 0.9%) NaCl. Sea water, containing approximately 0.5 M (3%) NaCl, can produce transient mild eye discomfort in some individuals. A salt concentration greater than 1 M or 2 Osm (twice that of sea water) is assigned a toxicity level 1 (critical) eye hazard. Some chemically reactive salts induce eye irritation or injury because they are strong oxidizers, e.g. sodium hypochlorite or potassium permanganate, or reducers, e.g. hydrazine. Certain chemicals have very specific affinity for and toxicity to the eye. For example, cobalt chloride can cause injury to the eye when it is applied topically to the eye

or given systemically. Because of these considerations, hazard levels are evaluated on a case-by-case basis for each solution. The reference book, *Toxicology of the Eye (W. M. Grant, 1986, Thomas Books),* is often used in assessing chemical irritancy.

4.08 Culture Media for Animal and Plant Cells, Whole Plants and Small Aquatic Animals.

Culture media for living organisms or cells generally contain nontoxic salts, nutrients, vitamins, trace minerals, buffering agents, and trace amounts of pH indicator. These solutions are generally neutral or slightly basic or acidic; the osmolarity of the solutions is usually compatible with life (i.e. not strongly hypertonic). Therefore, such media are generally assessed level 0. A standard culture medium may contain a long list of ingredients; the name of the medium, rather than the list of ingredients may be listed in the HMST.

4.09 Carcinogenic Compounds

It is rare that sufficient data exist on a given chemical to permit calculation of risk levels for carcinogenesis, particularly for relatively brief exposures. Generally, the JSC TG assumes that the increased risk of cancer due to brief exposures to most carcinogens is negligible, in the amounts generally used in payload experiments. For brief exposures, acute toxicity is generally a greater concern than carcinogenicity. The following relative risk guidelines have been adopted by the JSC TG for use in the rare cases when it is possible to quantitate the increased risk of cancer due to defined exposures.

Catastrophic: Increase in cancer risk greater than or equal to 1%
Critical: Increase in cancer risk of 0.01% up to 1%

Methods to quantitate the risks from cancer causing compounds are undergoing major change according to new EPA guidelines. The limitations of the linearized multistage model, which NASA has traditionally used, are being acknowledged and newer methods, such as the benchmark dose, are being explored.

4.10 Human Blood Products

Investigators or sponsors of payload experiments containing human blood products are required to provide certification or assurance that these products are free of infectious agents such as HIV and hepatitis B viruses. Blood products containing no cancer cells that are certified free from of these infectious agents are assessed a THL of 0.

4.11 Human Tumor Cells

Human cancer cells present a very low-risk of malignant colonization in a healthy host, however, accidental transplant of malignant human cells into healthy human recipients has been documented (Gartner et al. (New England Journal of Medicine 335:1494-1496, 1996); Scanlon et. al. (Cancer, 18:782-9, 1965), Gugel and Sanders (New England Journal of Medicine 315:1487, 1986)). Cultured cells could live only a few minutes if they were to somehow escape from the liquid culture medium. If cultured malignant cells were to reach the lungs, they would probably be destroyed by phagocytes and antibodies. These arguments, expert opinions, and regulatory guidelines were considered by the IRB in deciding that such cells are hazard level 0 (Appendix 5.08). Malignant cells from humans also must be screened for HIV and hepatitis B viruses.

4.12 Animal Cells and Tissues

Animal cells, except those derived from monkeys, are generally considered to be innocuous and are judged a level 0 hazard. Monkey cells may contain infectious agents that could cause illness in humans; therefore, these cells must be screened for specific viruses.

4.13 Microorganisms

Viruses, bacteria, and fungi are usually assessed for their potential health hazards by the JSC Microbiology Laboratory. Microbes used in spacecraft payload experiments are usually suspended in culture medium or cultured on nutrient agar. Most microbes, unless they are known to be highly virulent, are usually given a THL of 1. If they are immobilized in a gel or semi-solid matrix, the THL would be 0 unless the agent is very virulent. The major concern of escaped droplets containing high concentrations of infectious microbes is the potential of eye infection due to direct eye contact and possible ingestion after contact with the lips or hands. There is a small probability of the escaped droplets being inhaled and causing a respiratory tract infection. Many research strains of even common microbes have never been tested for their infectivity or pathogenicity, particularly for the eyes and respiratory tract. Thus, the JSC Microbiology Laboratory must often deal with a considerable amount of uncertainty in assessing such microbes.

4.14 Biochemical Products

DNA samples are usually regarded as non-hazardous. Proteins are evaluated on the basis of their biological activity. Viral proteins obtained as genetically engineered products are generally judged to be non-hazardous materials (THL = 0). Proteolytic enzymes will be evaluated for their ability to cause eye injury.

4.15 Radioactive Materials

Radioactive materials are assessed and assigned a radiation hazard level by the JSC Radioactive Payloads Working Group. Their assessment will be incorporated into the HMST.

4.16 Drugs or Chemicals to be Given to Crew Members During In-Flight Experiments

The biomedical hazard to crew member test subjects resulting from intentional administration of drugs, plasma expander, diagnostic agent, radioactive marker, respiratory gas or other chemical is evaluated by the IRB. The JSC-TG evaluates the toxic hazard potential (mainly eye irritancy) of compounds or solutions if they should escape their containment. Gaseous compounds to be inhaled by the test subject are assessed as described in Section 4.03.

4.17 Flammable Chemicals

The flammability hazard of large amounts of organic materials, materials with high volatility or those with appreciable explosive potential will be assessed by the JSC Materials and Failure Analysis Branch/EM2. Metals, most particulates, aqueous solutions, and organic compounds of low volatility will usually be rated as level 0 for flammability hazards.

Appendix 5.01

Flight Rule 13-21 *Hazardous Substance Spill Response*

13-21 HAZARDOUS SUBSTANCE SPILL RESPONSE

THE FLIGHT-SPECIFIC ANNEX WILL LIST ALL LEVEL 4 THROUGH LEVEL 1 PAYLOAD HAZARDOUS SUBSTANCES. REFERENCE RULE 13-22, HAZARDOUS SPILL LEVEL DEFINITIONS. THE FOLLOWING ACTIONS WILL BE TAKEN IN THE EVENT THAT A HAZARDOUS SUBSTANCE IS RELEASED INTO THE ORBITER ATMOSPHERE.

A. LEVEL 4

1. ALL CREWMEMBERS WILL DON AND ACTIVATE QUICK DON MASKS. THE CLEANUP CREW WILL TAKE THE FOLLOWING ACTIONS:

   a. SET CABIN TEMPERATURE CONTROLLER TO FULL COOL.

   b. TURN ON THE WASTE COLLECTION SYSTEM.

   c. TURN OFF THE REGENERATIVE CO_2 REMOVAL SYSTEM (RCRS) (IF APPLICABLE).

2. THE CREW SHALL PERFORM A CABIN DEPRESS AND REPRESS IF REQUIRED TO CONTROL PPO_2. (REFERENCE RULE 9-53, CABIN O_2 CONCENTRATION).

3. THE FLIGHT CONTROL ROOM SURGEON SHOULD BE CONSULTED FOR THE MAXIMUM LENGTH OF TIME THE QUICK DON MASKS CAN BE WORN. (REFERENCE RULE 13-10, 100 PERCENT OXYGEN CONSTRAINT.)

A level 4 hazardous substance is defined as either a gas, a volatile liquid, or fumes that are not containable by the crew. Crew exposure could result in systemic toxicity, severe irritation, and/or tissue damage. The driving factor that distinguishes a level 4 substance from a level 3 substance is noncontainability.

The immediate priorities for a level 4 spill are to prevent crew exposure to the substance and to configure the ARS to scrub the environment. All crewmembers will don and activate QDM's to avoid any debilitating effects.

THIS RULE CONTINUED ON NEXT PAGE

13-21 HAZARDOUS SUBSTANCE SPILL RESPONSE (CONTINUED)

The ARS configuration steps were determined to provide maximum decontamination. Setting the cabin temperature to full cool will provide maximum removal of water soluble or particulate hazardous substances through the humidity separator as condensate. Other atmospheric scrubbing can be accomplished with the use of the odor/bacterial filter of the WCS and the LiOH and/or charcoal canisters that are already installed. The most recently installed LiOH canisters may have exhausted CO_2 removal capability; however, the LiOH/CO_2 product, Li_2CO_3, and existing charcoal still have scrubbing potential. For flights that use the RCRS, the RCRS must be unpowered to prevent contamination of the solid amine.

A depress and repress of the cabin will lower the O_2 concentration levels as well as the concentration of the level 4 substance. This action could extend the time on orbit so as to avoid an ELS entry.

B. LEVEL 3

1. ALL CREWMEMBERS WILL DON AND ACTIVATE QUICK DON MASKS AND SILVER SHIELD GLOVES. THE FLIGHT DECK CREW WILL TURN OFF THE CABIN AND IMU FANS ONE CREWMEMBER WILL CONTINUOUSLY MONITOR THE SPILL. THE CLEANUP CREW WILL TAKE THE FOLLOWING ACTIONS:

   a. ATTEMPT TO CLEAN UP THE SPILL.

   b. BAG, LABEL AND STOW IN WET TRASH.

2. IF CLEANUP ATTEMPT FAILS, THE HAZARDOUS SPILL WILL BE UPGRADED TO A LEVEL 4.

A level 3 hazardous substance is defined as a solid or nonvolatile liquid that is containable by the cleanup crew. It is this containability that separates a level 3 substance from a level 4.

Crew exposure to a level 3 substance could result in systemic toxicity, severe irritation, and/or tissue damage. It is this severity of effects on exposure that separates a level 3 substance from the levels 2, 1, and 0 substances. All crewmembers must wear QDM's to protect themselves during the cleanup.

During the cleanup, all airflow is halted by deactivating the cabin and IMU fans to prevent dispersion of the spilled substance. The maximum time that a cabin fan can be deactivated in an off-nominal situation is 20 minutes (ref. SODB, Volume 3, Rev. A, Table 4.5.0-1, Display Driver Unit). The maximum time that an IMU fan can be deactivated in an off-nominal situation is 45 minutes, (ref. SODB, Volume 3, Rev. A, Table 4.5.0-1, Inertial Measuring Unit).

By definition, a level 3 hazardous spill is catastrophic and containable. If the level 3 cleanup fails, this spill will be upgraded to a level 4, and level 4 cleanup actions shall be implemented.

THIS RULE CONTINUED ON NEXT PAGE

13-21 HAZARDOUS SUBSTANCE SPILL RESPONSE (CONTINUED)

C. LEVEL 2

1. ALL CREWMEMBERS WILL DON GOGGLES, SURGICAL MASKS, AND SILVER SHIELD GLOVES. THE FLIGHT DECK CREW WILL TURN OFF THE CABIN AND IMU FANS. THE CLEANUP CREW WILL TAKE ACTIONS A AND B LISTED IN PARAGRAPH B ABOVE.

2. IF CLEANUP ATTEMPT FAILS, THE HAZARDOUS SPILL WILL BE UPGRADED TO A LEVEL 4.

A level 2 substance is either a solid or a nonvolatile liquid that is containable by the cleanup crew. Crew exposure could result in moderate to severe irritation that has the potential for long-term crew performance decrement. All crewmembers will be adequately protected by the 5-micron surgical masks, goggles, and silver shield gloves.

See paragraph B, level 3 rationale, for the reason for stopping the airflow in the spill area.

Even though a level 2 substance causes less severe effects than a level 3 substance, a level 2 spill is defined as catastrophic and containable. If the level 2 cleanup fails, this spill will be upgraded to a level 4, and level 4 cleanup actions shall be implemented.

D. LEVEL 1

ALL CREWMEMBERS WILL DON GOGGLES AND SURGICAL MASKS. THE FLIGHT DECK CREW WILL TURN OFF THE CABIN AND IMU FANS. THE CLEANUP CREW WILL DON SURGICAL GLOVES AND TAKE ACTIONS a AND b LISTED IN PARAGRAPH B.

A level 1 hazardous substance may or may not be containable by the crew. Crew exposure will result only in slight to moderate irritation. All crewmembers will be protected by surgical masks and goggles.

See paragraph B, level 3 rationale, for the reason for stopping the airflow in the spill area.

If the spill is not containable by the crew, the MCC will determine other procedures for containment or for a workaround.

THIS RULE CONTINUED ON NEXT PAGE

13-21 HAZARDOUS SUBSTANCE SPILL RESPONSE (CONTINUED)

E. LEVEL 0

THE FLIGHT DECK CREW WILL TURN OFF THE CABIN AND IMU FANS. THE CLEANUP CREW WILL TAKE ACTIONS a AND b LISTED IN PARAGRAPH B.

A level 0 substance may or may not be containable by the crew. Crew exposure would result in only slight transient (less than 30 minutes) irritation.

No protective gear is required.

See paragraph B, level 3 rationale, for the reason for stopping the airflow in the spill area.

If the spill is not containable by the crew, the MCC will determine other procedures for containment or for a workaround.

All payload substances are reviewed by the Payload Safety Review Panel; those not listed as level 4 through 1 are considered nonhazardous (level 0).

Appendix 5.02

Estimation of the Rate of Removal of Toxic Vapors and Fumes From the Cabin Atmosphere

The estimated length of time required for the ARS to reduce the concentration of an escaped gas or particulates to a non toxic level is the most frequently used determinant of the likely duration of crew exposure. Some applicable data used in estimating the length of time required to scrub toxic gases and particulates by several of the major ARS components is listed below.

Table 3
Air Revitalization Systems in the Shuttle Cabin

ARS Component*	Scrubber Material	Mesh Size(μm)	Rate of Airflow(m^3/hr)
Orbiter Cabin Fan Filter	steel mesh	40 - 70	497 - 578
Orbiter Cabin Air Cleaner	steel mesh	38.5	340 - 1020 (adjustable)
Carbon Dioxide Absorber Element (CDAE)(2 units)	lithium hydroxide (2.3 kg each) charcoal (110 g each)	N/A	92 (both units)
Condensing Heat Exchanger (CHX)	cold condenser coils	N/A	232 -529**
Orbiter Vacuum Cleaner	filter paper	about 20 μm	60

*The listed ARS devices would be assisted to some degree by less important ARS devices which are not listed here.

**The rate of airflow through the CHX is determined by the cabin temperature and the thermostat setting.

Although only a small amount of charcoal is in the CDAE LiOH canisters, these canisters are changed out at 6 - 8 hour intervals, so a sizable amount of a contaminant could be scrubbed within 24 hours. The efficiency of charcoal air filters in removing a toxic gas depends largely on the molecular volume, molecular polarity and reactivity of the gas. Examples:

Ethyl alcohol (CH_3CH_2OH) is much better adsorbed than methyl alcohol (CH_3OH) due to its greater molecular volume.

Ethyl alcohol (CH_3CH_2OH) is much better adsorbed than propane ($CH_3CH_2CH_3$) due its greater polarity and reactivity.

Some examples of the relative activated charcoal adsorbencies of some typical chemicals of interest to the space program are listed below:

Well adsorbed: benzene, , ethyl acetate, trichloroethylene, Freon 12 (CCl_2F_2)

Fairly well adsorbed: acetone, Freon 21 ($CHCl_2F$), hydrogen cyanide (HCN)

Poorly adsorbed: methane, ethylene, carbon dioxide, carbon monoxide.

Fortunately, most toxic compounds are also rather reactive and are well adsorbed on charcoal. Exceptions are low molecular weight compounds such as formaldehyde. However, a special chemically-treated charcoal commonly used in glovebox experiments readily adsorbs formaldehyde.

The efficiency of the condensing heat exchanger (CHX) in removing a specific airborne vapor depends largely on its water solubility and vapor pressure. For example, ethylene glycol, which is completely water soluble and has a low vapor pressure, would be expected to readily condense out in the CHX.

In estimating the rate of removal of a contaminant vapor by the ARS charcoal beds, the toxicologist usually assumes that it would not be completely removed at one flowthrough. Therefore, if the concentration of an escaped vapor that is well adsorbed on charcoal were 5 times the SMAC, a volume of air equivalent to the modular volume would probably have to pass through a charcoal bed two to three times to reduce the vapor's concentration to below the SMAC. If the toxic gas were only fairly well adsorbed by charcoal, it might have to pass through the charcoal bed five to seven times before it was reduced to the SMAC level.

Particulates- Considering the high rate of air movement and the rather straight walls in most areas of the habitable modules (see above), escaped particulates greater than 40 μm (the lower limit of visibility by most individuals) would move fairly well with the cabin airflow and would be readily filtered by the cabin fan filter and the avionics filters. Larger particles (5 mm) would move more slowly with the cabin airflow due to inertia and would therefore be filtered more slowly. It is very likely that particulates much smaller than 40 μm would be filtered due to electrostatic attractions towards the above filters, but since this has not been proven, the toxicologists rely on only the above filters for removing particulates >40 μm in establishing the possible durations of crew exposure. Smaller particles may be removed by the Orbiter vacuum cleaner (OVC) (airflow of about 60 m^3/hour) since the mesh size of the paper filter cone in the OVC is about 20 μm (statement by the manufacturer's representative). Five reserve OVC filter cones (volume of 0.75 liters each), manifested in the Shuttle during each mission, provide the capability of removing a rather large volume of toxic or nuisance dusts.

It is assumed that very small particulates (5 μm or less) would be eventually removed from the Shuttle atmosphere due to electrostatic attraction to the various Shuttle surfaces, aggregation with other particulates, and entrapment by the humidity condensate in the condensing heat exchanger (cabin dehumidifier). Therefore, the toxicologists generally assume that the crew would be exposed to toxic concentrations of very fine dusts, as metal fumes, for no longer than 24 hours.

Appendix 5.03

Procedures for Accessing Payload -Specific Data on the Internet

The mission-specific Flight Requirements Document (FRD) can be accessed on the Internet as follows:

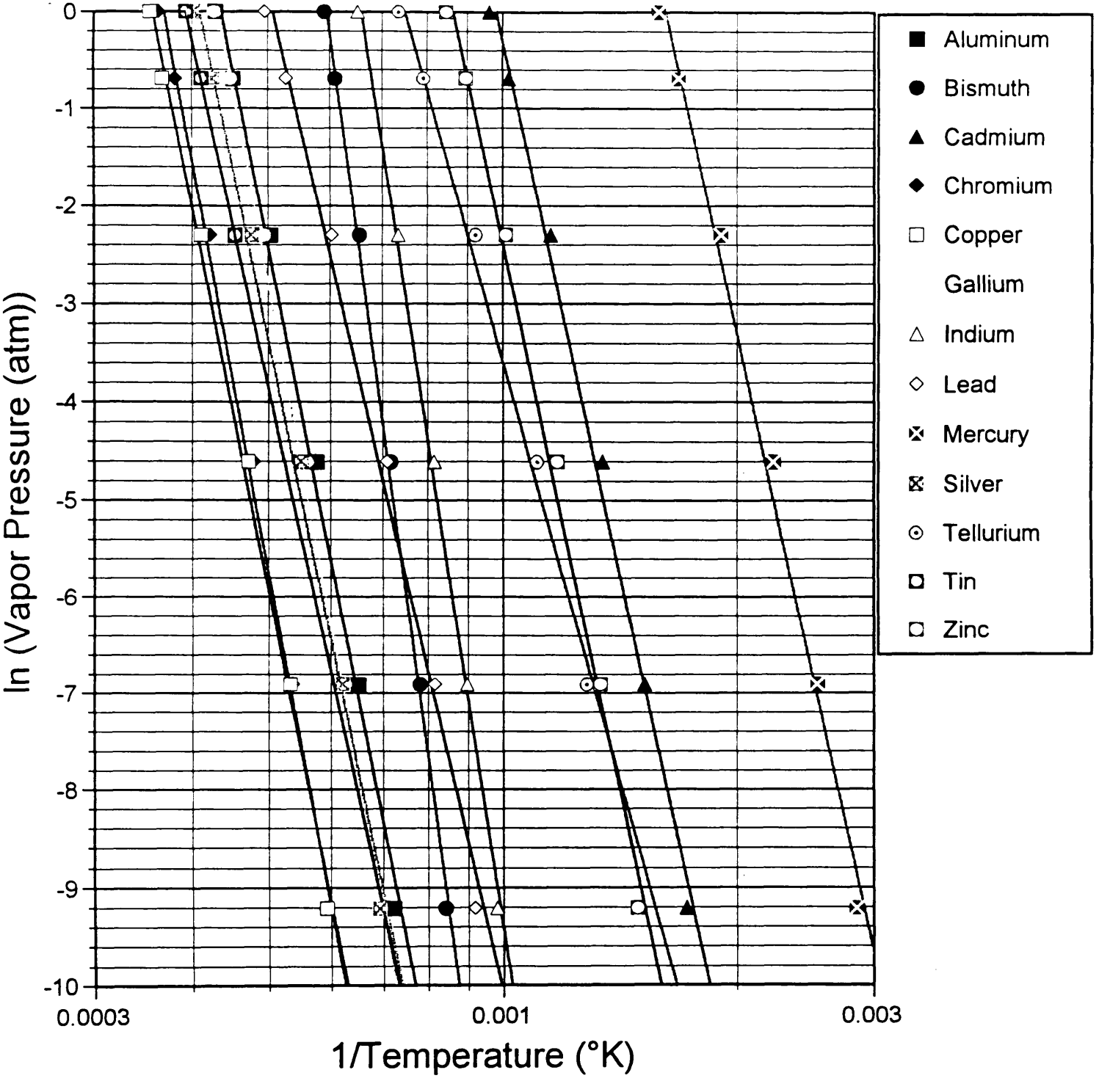
Connect to the JSC Payload Information Library System (PILS) Home Page PILS at
http://sspweb.jsc.nasa.gov/pils.
Click on the grey "PILS" button to start the PILS application.
Click on the grey "Misc" button.
Scroll down the list to find the FRD for the desired mission.
Click on the blue FRD text (NSTS 17462-## FRD) for the desired mission.

A list of DSO, DTO, and RME experiments and the payload safety engineers responsible for each is available as Microsoft Excel documents on the Internet at the following address:

http://wwwsrqa.jsc.nasa.gov/pcehome.htm

Appendix 5.04

Curves of Vapor Pressure versus Temperature for Various Metals



Appendix 5.05

Letter From the Chairman of the Human Research Policy and Procedures Committee to the Chairman of the Payload Safety Review Panel on *Catastrophic and Critical Levels of Metallic Fumes and Dusts*

Space Administration

Lyndon B. Johnson Space Center
Houston, Texas
77058

JUN 19 1991

Reply to Attn of SD4/91-198

TO: TA/Chairman, Payload Safety Review Panel

FROM: SA/Chairman, Human Research Policies and Procedures Committee (HRPPC)

SUBJECT: Catastrophic and Critical Levels of Metallic Fumes or Dusts

Your Payload Safety Review Panel (PSRP) requested that the JSC Toxicology Group estimate the concentrations of metal dusts and fumes (particles equal to or less than 1 micron) following a one-time release from a furnace into a spacecraft internal environment that would pose a critical hazard (potentially causing mild to moderate levels of annoyance, irritation, and/or illness) or a catastrophic hazard (potentially causing severe levels of annoyance, irritation, illness or incapacitation). I understand that the PSRP needs these estimates to establish containment levels and other safeguards required in metal processing experiments during space flight.

The JSC Toxicology Group has estimated that if a sudden release of a metallic dust or fumes exceeds the American Conference of Governmental Industrial Hygienists (ACGIH) industrial workplace threshold limit value (TLV), there is a small, but significant, risk of adverse effects, so this level would be regarded as a critical hazard. If the initial concentration of a metal dust or fume were more than 10 times its TLV, there would be a small, but significant risk, of severe adverse effects; so this level would be regarded as a catastrophic hazard. The TLV's were established by the ACGIH "to represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects."

I hope that these toxicity criteria will be of value to you in your safety assessments of metal processing payload experiments. Please keep in mind that the present evaluation of concentrations versus hazard levels is applicable only to metal dusts and fumes.

Lawrence F. Dietlein, M.D.

Appendix 5.06

Summary of the Primary Irritant Effects of Various Concentrations of Glutaraldehyde

From Union Carbide's Material Safety Data Sheet for Glutaraldehyde: "Review of Toxicological Studies and Human Health Effects" (1986).

Summary of primary irritant effects of various concentrations of glutaraldehyde on the rabbit eye: six animals per group

Glutaraldehyde Concentration, % w/w	Volume Instilled, ml	Observations
5.0	0.1	Persistent severe keratitis, corneal neovascularization, severe necrotizing blepharitis and conjunctivitis.
	0.01	Delayed onset minor to moderate corneal injury with moderate to marked conjunctivitis, persisting for 2 to 3 weeks.
	0.005	Minor transient (24 hr) corneal injury with moderate to marked conjunctivitis persisting for up to 2 weeks.
2.0	0.1	Minor corneal injury at 2 to 3 days, with moderate to marked conjunctivitis persisting for 2 to 3 weeks.
	0.01	Moderate conjunctivitis of about 3 days duration, but no corneal injury.
	0.05	Minor to moderate conjunctivitis of about 3 days duration without corneal injury.
1.0	0.1	Minor corneal injury at 2 to 7 days with moderate to marked conjunctivitis persisting for up to 2 weeks.
	0.01	Minor to moderate conjunctivitis of 2 to 3 days duration without corneal injury.
0.5	0.1	Mild injection of conjunctiva of 48 hours duration. No corneal injury.
	0.01	Minimal injection of conjunctivae of less than 24 hours duration. No corneal injury.
0.2	0.1	Minimal injection of conjunctivae of 24 hours duration. No corneal injury.
	0.01	No effects.
0.1	0.1	No effects.
	0.01	No effects.

Appendix 5.07

Acidity and Basicity of Some Common Liquids

From Handbook of Chemistry and Physics, CRC Press, 65th edition, page D-150

APPROXIMATE pH values

The following tables give approximate pH values for a number of substances such as acids, bases, foods, biological fluids, etc. All values are rounded off to the nearest tenth and are based on measurements made at 25 C. A few buffer systems with their pH values are also given.

From Modern pH and Chlorine Control, W. A. Taylor & Co.

ACIDS

Hydrochloric, N 0.1	Oxalic, 0.1N 1.6	Acetic, 0.01N 3.4
Hydrochloric, 0.1N 1.1	Tartaric, 0.1N 2.2	Benzoic, 0.01N 3.1
Hydrochloric, 0.01N 2.0	Malic, 0.1N 2.2	Alum 3.2
Sulfuric, N 0.3	Citric, 0.1N 2.2	Carbonic (saturated) 3.8
Sulfuric, 0.1N 1.2	Formic, 0.1N 2.3	Hydrogen sulfide, 0.1N 4.1
Sulfuric, 0.01N 2.1	Lactic, 0.1N 2.4	Arsenious (saturated) 5.0
Orthophosphoric, 0.1N 1.5	Acetic, N 2.4	Hydrocyanic, 0.1N 5.1
Sulfurous, 0.1N 1.5	Acetic, 0.1N 2.9	Boric, 0.1N 5.2

BASES

Sodium hydroxide, N 14.0	Lime (saturated) 12.4	Magnesia (saturated) 10.5
Sodium hydroxide, 0.1N 13.0	Trisodium phosphate, 0.1N 12.0	Sodium sesquicarbonate, 0.1M 10.1
Sodium hydroxide, 0.01N 12.0	Sodium carbonate, 0.1N 11.6	Ferrous hydroxide (saturated) 9.5
Potassium hydroxide, N 14.0	Ammonia, N 11.6	Calcium carbonate (saturated) 9.4
Potassium hydroxide, 0.1N 13.0	Ammonia, 0.1N 11.1	Borax, 0.1N 9.2
Potassium hydroxide, 0.01N 12.0	Ammonia, 0.01N 10.6	Sodium bicarbonate, 0.1N 8.4
Sodium metasilicate, 0.1N 12.6	Potassium cyanide, 0.1N 11.0	

Appendix 5.08

Letter From the Chairman of the Human Research Policy and Procedures Committee to the Chairman of the Payload Safety Review Panel on Hazard Assessment of Cell Cultures

Reply to Attn of SD4-92-468

JAN 13 1993

TO: TA/Manager, Payload Safety Review Panel

FROM: SA/Chairman, Human Research Policy and Procedures Committee

SUBJECT: Hazard Assessment of Cell Culture

The Payload Safety Review Panel requested that the Human Research Policy and Procedures Committee (HRPPC) evaluate the biological hazard potential of the human myeloma cells to be used in the STS-55 Spacelab D-2 Biolabor BB-HYBRI experiment (enclosure 1). During the mission, these cells will be combined by electrofusion with human B or T lymphocytes to form self-replicating hybridoma cells. The *in vitro* myeloma cell culture will be maintained in a sealed cell culture bag; portions of the cells will be removed at various times through special access ports into triple-contained syringes (enclosure 2). The single level of containment offered by the cell-culture bag would not be adequate were there an unacceptable risk of their causing a malignancy or viral infection should they escape. The primary concern is, that should these cells escape, they might be inhaled and then colonize in the lungs or cause a viral infection.

Our life sciences representative on your panel, and one of his support contractors, discussed the health risk from the myeloma cell culture system with five outside cell culture researchers and four JSC researchers with special knowledge and expertise in hybridoma cell cultures. From these discussions, we have concluded that the risk of cancer from the *in vitro* myeloma cells would be extremely low. If the growth medium were to escape, it would be expected to escape as liquid globules; these globules could not get past the nasal area if inhaled. If these released media globules were to dry out, the myeloma cells could live for only a few minutes without the liquid. If these rather large myeloma cells were still alive when inhaled, they would be trapped by the mucous secretions of the upper respiratory tract and then swept out by the ciliary system. The first line of defense, the mucous secretions and several layers of epithelium cells, would make it impossible for the malignant cells to implant in the upper respiratory tract area. If the myeloma cells did somehow reach the lungs and implant, they would be immediately engulfed and destroyed by the phagocytes in the body's non-specific surveillance system.

In answer to the concern over the risk of a viral infection, Dr. Gary Neil, one of the co-investigators for the study, said that the myeloma cell culture had been screened for the HIV, hepatitis B and C, and Epstein Barr viruses. The myeloma cells are the progeny of many generations of cells kept in cultures; they all initially came from the same patient. Dr. Neil added that his own staff has handled the cells for several years, with only the usual safeguards for handling biological materials. To his knowledge, no one has contracted a viral or malignant disease from these cells. If Dr. Neil and his workers had considered the cells to be hazardous, they would have worked under much more stringent conditions.

Considering the above factors, the HRPPC has established that the health risk from the human myeloma cells in the Biolabor BB-HYBRI experiment is extremely low, and that the presently-designed experiment is therefore safe for flight.

Lawrence F. Dietlein, M.D.

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